

Appl. No. : 10/700,355
Filed : November 3, 2003

REMARKS

The following remarks are responsive to the July 13, 2007 Advisory Action. Claims 1-10, 14, and 15 were previously cancelled without prejudice, Claim 11 is amended, Claims 12, 13, 16, and 17 remain as originally filed, Claims 18 and 19 remain as previously presented, and new Claims 20-27 are added. Thus, Claims 11-13 and 16-27 are presented for further consideration.

Response to Rejection of Claims 11-13 and 17-19 Under 35 U.S.C. § 103(a)

In the July 13, 2007 Advisory Action, the Examiner reaffirms the rejection of Claims 11-13 and 17-19 in the April 24, 2007 Final Office Action under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,063,108 issued to Salansky *et al.* ("Salansky").

As described herein, Applicant has amended Claim 11 to recite (emphasis added):

11. A method for accelerating the production of a vaccine by an in vitro cell culture, the method comprising:
- providing an in vitro cell culture comprising cells useful in production of a vaccine, the cells comprising bacteria useful for vaccines or animal cells containing viruses useful for vaccines; and
 - enhancing the in vitro cell culture by delivering an effective amount of electromagnetic energy to the in vitro cell culture, wherein delivering the effective amount of electromagnetic energy includes delivering electromagnetic energy having a power density of at least about 0.01 mW/cm² and a wavelength of about 780 nm to about 840 nm to the cells in the in vitro cell culture.

Applicant submits that amended Claim 11 is fully supported by the application as originally filed, including but not limited to, paragraphs [0002]-[0004], [0009], and [0010].

Applicant respectfully traverses the rejection of Claim 11. Applicant submits that amended Claim 11 includes features which are not disclosed or suggested by Salansky. For example, Salansky does not disclose or suggest "providing an in vitro cell culture comprising cells ... comprising bacteria useful for vaccines or animal cells containing viruses useful for vaccines," as recited by amended Claim 11. Salansky teaches the use of low energy photon therapy (LEPT) applied to the patient's body to treat a variety of disorders of biological tissue or their symptoms (see, e.g., Salansky at column 5, lines 40-53). While Salansky discloses previous cell cultures studies, nowhere does Salansky disclose or suggest that these cell cultures comprised "bacteria useful for vaccines or animal cells containing viruses useful for vaccines," and persons skilled in the art would not be motivated to modify Salansky to provide such cell cultures.

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Furthermore, Salansky does not disclose or suggest “enhancing the *in vitro* cell culture” as recited by amended Claim 11. While Salansky discloses that the clinical treatment protocols of LEPT are developed in part based on “data from cell culture & animal studies” (see, Figure 1 of Salansky), Salansky does not disclose or suggest that these cell culture studies were performed so as to enhance the cell culture, as recited by amended Claim 11. In fact, Salansky is silent about the details of these cell culture studies, providing no information on the types of cells, the optical parameters, or experimental conditions used. All that is disclosed by Salansky is that some cell culture was irradiated by some light under some conditions. Applicant submits that persons skilled in the art would not be motivated by Salansky to enhance “an *in vitro* cell culture ... comprising bacteria or animal cells containing viruses useful for vaccines,” as recited by amended Claim 11.

Applicant incorporates by reference herein in its entirety the argument, previously submitted in response to the April 24, 2007 Final Office Action, that Salansky teaches away from applying the disclosed parameters for *in vivo* irradiation to the irradiation of *in vitro* cell cultures, and that persons skilled in the art would not expect that such application of *in vivo* irradiation parameters to work for *in vitro* irradiation of cell cultures. In the July 13, 2007 Advisory Action, the Examiner rebuts this argument by stating that:

Although the parameters may not be identical between *in vivo* and *in vitro* applications as applicant argued, the reference teaches the method used in *in vitro* experiments and it would have been obvious for a person of ordinary skill in the art to routinely modify such parameters.

However, Applicant submits that the *in vitro* cell culture studies alluded to by Salansky were used to provide information relevant to the subsequent development of clinical *in vivo* treatment protocols for LEPT applied to a patient’s body (see, Figure 1 of Salansky). Applicant further submits that there is no motivation for persons skilled in the art to take the presumably successful *in vivo* LEPT treatment protocols disclosed by Salansky and to go back and apply, modify, or optimize them for *in vitro* cell cultures. Applicant submits that without such a motivation, the Examiner has not satisfied the conditions for *prima facie* obviousness.

For at least the above-stated reasons, Applicant submits that amended Claim 11 is patentably distinguished over Salansky. Each of Claims 12, 13, and 17-19 depends either directly or indirectly from amended Claim 11, so each of these claims includes all the features of amended Claim 11 as well as other features of particular utility. Therefore, Applicant

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respectfully requests that the Examiner withdraw the rejection of Claims 11-13 and 17-19 and pass these claims to allowance.

Response to Rejection of Claims 11, 12, and 16 Under 35 U.S.C. § 103(a)

In the July 13, 2007 Advisory Action, the Examiner maintains the rejection of Claims 11, 12, and 16 under 35 U.S.C. § 103(a) as being unpatentable over van Breugel et al., *Lasers in Surgery and Medicine*, 1992, Vol. 12, pages 528-537 (“van Breugel”).

Applicant respectfully traverses this rejection. In particular, Applicant submits that amended Claim 11 includes features which are not disclosed or suggested by van Breugel. For example, van Breugel does not disclose or suggest “providing an *in vitro* cell culture comprising cells ... comprising bacteria useful for vaccines or animal cells containing viruses useful for vaccines,” as recited by amended Claim 11. While van Breugel discloses an *in vitro* photobiomodulation study of human fibroblast cells, nowhere does van Breugel disclose or suggest that these cell cultures comprised “bacteria useful for vaccines or animal cells containing viruses useful for vaccines,” and persons skilled in the art would not be motivated to modify van Breugel to provide such cell cultures.

Furthermore, van Bruegel does not disclose or suggest “enhancing the *in vitro* cell culture” as recited by amended Claim 11. Applicant incorporates by reference herein in its entirety the argument, previously submitted in response to the April 24, 2007 Final Office Action, that van Bruegel does not teach “a wavelength of about 780 nm to about 840 nm,” as recited by Claim 11. In the July 13, 2007 Advisory Action, the Examiner rebuts this argument by stating that:

it would have been obvious for a person of ordinary skill in the art to modify such result effective variables for cell types other than human fibroblasts, and a person of ordinary skill in the art would have been [sic] tried different wavelength including [sic] the range of 780 to 840 nm for other types of cells.

At page 535, first column, line 49 – second column, line 11, van Breugel teaches that “[a] photobiological response entails the absorption of a specific wavelength of light,” that such wavelengths correspond to some of the absorption peaks of the cells, and that other wavelengths are less effective. Applicant submits that in view of this teaching of van Bruegel, persons skilled in the art would not try different wavelengths that did not correspond to absorption wavelengths of the cells of the cell culture. The Examiner is assuming that there are cells having absorption peaks in the range recited by amended Claim 11 and that cultures of such cells would be

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enhanced by such irradiation. In particular, applied to amended Claim 11, such an argument assumes that cell cultures comprising "bacteria useful for vaccines or animal cells containing viruses useful for vaccines" would be enhanced by the wavelengths recited by amended Claim 11. The Examiner has not provided any basis for such assumptions beyond the teachings of the present application. Applicant submits that by relying on the present application in this way, the pending rejection is based on an impermissible use of hindsight derived from the teaching of the present application. See, e.g., In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999).

For at least the above-stated reasons, Applicant submits that amended Claim 11 is patentably distinguished over van Breugel. Each of Claims 12 and 16 depends from Claim 11, so for at least the same reasons, these claims are also patentably distinguished over van Breugel. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 11, 12, and 16 and pass these claims to allowance.

Comments on New Claims 20-27

Applicant has added new Claims 20-27. Applicant submits that these new claims are fully supported by the present application as originally filed, including but not limited to, paragraphs [0012], [0017], and [0021].

Each of Claims 20-24 depends either directly or indirectly from amended Claim 11, so each of these claims includes all the features of amended Claim 11 as well as other features of particular utility. Therefore, for at least the same reasons as stated above, Applicant submits that Claims 20-24 are patentably distinguished over the prior art. Furthermore, Applicant submits that each of Claims 25-27 includes features that are not disclosed or suggested by the prior art, so that Claims 25-27 are patentably distinguished over the prior art. Applicant respectfully requests that the Examiner pass Claims 20-27 to allowance.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution.

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Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending application of the present application's assignee.

Serial Number	Title	Filed
11/339,993	Enhancement of in vitro culture or vaccine production in bioreactors using electromagnetic energy	January 26, 2006

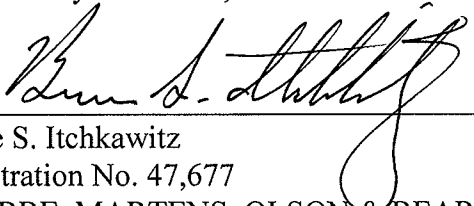
Summary

For at least the above-stated reasons, Applicant submits that Claims 11-13 and 16-27 are in condition for allowance, and Applicant respectfully requests such action.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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